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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
| 10/539,032   | 06/13/2005  | Ken-ichi Inui        | 4439-4034                | 8848             |
| 27123  | 7590        | 05/14/2008           |                          |                  |
| MORGAN & FINNEGAN, L.L.P.<br>3 WORLD FINANCIAL CENTER<br>NEW YORK, NY 10281-2101 |             |                      | EXAMINER<br>LI, RUIXIANG |                  |
|  |             |                      | ART UNIT                 | PAPER NUMBER     |
|  |             |                      | 1646                     |                  |
|  |             |                      | NOTIFICATION DATE        | DELIVERY MODE    |
|  |             |                      | 05/14/2008               | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOPatentCommunications@Morganfinnegan.com  
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|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/539,032 | <b>Applicant(s)</b><br>INUI ET AL. |  |
|                              | <b>Examiner</b><br>RUIXIANG LI       | <b>Art Unit</b><br>1646            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7-9,14-17,19 and 21-29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 2,6, 10-13, and 30 is/are rejected.
- 7) ☒ Claim(s) 1,18 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of Application, Amendments, and/or Claims**

The amendment filed on 02/28/2008 has been entered. Claim 30 is added. Claims 1-30 are pending. Claims 1-3, 6, 10-13, 18, 20, and 30 are currently under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

### **Withdrawn Objections and/or Rejections**

The rejection of claims 1-3 under 35 U.S.C. §101 is withdrawn in view of amended claims.

The rejection of claims 1, 3, 18, and 20 under 35 U.S.C. §101 is withdrawn in view of amended claims.

The rejection of claim 1 under 35 U.S.C. 102(e) as being anticipated by Isogai et al. (U.S. Patent No. 6,943,241 B2, September 13, 2005; 102 (e) date: 1/25/2002) is withdrawn in view of amended claim.

The objections to claims 1-3, 6, 10-13, 18, and 20 are withdrawn in view of amended claims.

**Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph**

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 2, 6, 10-13 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for the instantly claimed genus of DNA molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that claim 2 is directed to an isolated DNA that hybridizes with the DNA of claim 1. Applicants argue that the claims are sufficiently enabled by the specification.

Applicants' argument has been fully considered, but is not deemed to be persuasive because claim 2, as written, encompasses a genus of DNA that hybridizes with DNA of SEQ ID NO: 1 or the complementary sequence of SEQ ID NO: 1. Claims 6, 10-13 and 30 depend from claims. While providing sufficient guidance and/or working examples with respect to make and use the DNA molecule that encodes the polypeptide of SEQ ID NO: 2, the instant disclosure fails to provide sufficient guidance and/or working examples to make and use the variants of DNA molecule that hybridizes with the DNA

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of SEQ ID NO: 1 or the complementary sequence of SEQ ID NO: 1. It is unpredictable whether a variant would retain the same function as that of the full length of polypeptide of SEQ ID NO: 2. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein. Furthermore, the state of the art is such that determining the specificity of hybridization is empirical by nature and the effect of mismatches is unpredictable, as taught by Wallace et al. (Methods Enzymol. 152:432-443, 1987) and Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2<sup>nd</sup> Edition, 1989, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, page 11.47). It is well known in the art that hybridization yields nucleic acids that are structurally related, but functionally different. Thus, in view of the nature of complexity of the work and unpredictability of the art, it would take undue experimentation for one skilled in the art to make and use the claimed genus of DNA molecules without sufficient guidance, working examples, and knowledge about functions of encompassed DNA molecules structurally related to SEQ ID NO: 1.

Accordingly, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the DNA molecules commensurate in scope with these claims.

(iii). Claims 2, 6, 10-13 and 30 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants argue that claim 2 is directed to an isolated DNA that hybridizes with the DNA of claim 1. Applicants argue that the claims comply with the written description requirement.

Applicants' argument has been fully considered, but is not deemed to be persuasive because claim 2, as written, encompasses a genus of DNA that hybridizes with DNA of SEQ ID NO: 1 or the complementary sequence of SEQ ID NO: 1. Claims 6, 10-13 and 30 depend from claims. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case, a single DNA of SEQ ID NO: 1 is not sufficient to support the broad genus of claimed DNA molecules. Claims 6, 10-13 and 30 are rejected as dependent claims.

**Claim Rejections under 35 USC§ 112, 2<sup>nd</sup> paragraph**

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 2, 6, 10-13, 18, 20, and 30 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(iii). Claim 2 recites “under stringent conditions”, but merely indicates the temperature at which the hybridization is carried out. Since neither the specification nor the art provides an unambiguous definition for the term, rendering the claim indefinite. Claims 10-13 and 30 are rejected as dependent claims from claim 2.

Applicants argue that the claim has been amended to include a stringent condition. This is not found to be persuasive because claim 2 recites merely the temperature at which the hybridization is carried out, not the complete hybridization conditions.

(iv). Claims 18 and 20 are indefinite because they recite “the functionality of the glucose or fructose transporter”. It is unclear what the metes and bounds of the preamble are.

Applicants argue that claim 18 has been amended to be directed to a probe for diagnosing the functionality of the glucose or fructose transporter. This is not found to be persuasive because the specification fails to define the term unambiguously.

### **Claim Objections—Minor Informalities**

Claims 1 and 18 are objected to because they recite “the base sequence of SEQ ID NO: 1”, which should be amended to be “the nucleotide sequence of SEQ ID NO: 1” or “the nucleic acid sequence of SEQ ID NO: 1”.

Claims 13 and 30 are objected to because they recite “an animal tissue cell expressing a polypeptide which has glucose or fructose transporter function”, which do not sufficiently distinguish over an animal tissue cell that exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified”. See MPEP 2105.

Appropriate correction is required.

### **Conclusion**

Claim 3 is allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.

May 12, 2008